

IN THE CLAIMS:

Please cancel claims 1, 3-7, 12-14, 19, 20, 24-26, and 39-45 without prejudice or disclaimer. Please amend claims 8-11, 16-18, 21-23, 27-32 and 34-38 as set forth below. Applicants note that all claims currently pending in the application are shown below for clarity, except claims 1, 3-7, 12-14, 19, 20, 24-26, and 39-45, which are canceled herein.

1
8. (Amended) A stable non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same, the ratios of the two components are in the range of 40:60 to 60:40, and the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

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9. (Amended) A stable non-aqueous single phase biocompatible viscous vehicle which comprises three components selected from the group consisting of solvent, surfactant, and polymer, wherein the components are not the same, wherein the ratios of the components are in the range of about 30% to about 50% for solvent, about 5% to about 20% for surfactant, and about 5% to about 60% for polymer, and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

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10. (Amended) A stable non-aqueous single phase biocompatible viscous vehicle which comprises three components selected from the group consisting of solvent, surfactant, and polymer, wherein the components are not the same, wherein the polymer is polyvinylpyrrolidone, the surfactant is glycerol monolaurate, and the solvent is lauryl lactate, and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

201
Amended
11. (Amended) A stable non-aqueous single phase biocompatible viscous vehicle which comprises three components selected from the group consisting of solvent, surfactant, and polymer, wherein the components are not the same, wherein the polymer is polyvinylpyrrolidone, the surfactant is polysorbate, and the solvent is lauryl lactate, and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

16. (Amended) A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate and is stable at body temperature for extended periods of time, the stable non-aqueous viscous protein formulation comprising:

- 202
- a) at least one beneficial agent; and
 - b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

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17. (Amended) A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising:

- a) at least about 0.1% (w/w) beneficial agent; and
- b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

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18. (Amended) A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising:

- a) at least about 10% (w/w) beneficial agent; and
- b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

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21. (Amended) A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate and is stable at 65° C for at least about 2 months, the stable non-aqueous viscous protein formulation comprising:

- 22 cont.
- a) at least one beneficial agent; and
 - b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

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22. (Amended) A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate and is stable at 37° C for at least about 3 months, the stable non-aqueous viscous protein formulation comprising:

- a) at least one beneficial agent; and
- b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

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23. (Amended) A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate and is stable at 37° C for at least about one year, the stable non-aqueous viscous protein formulation comprising:

- a) at least one beneficial agent; and
- b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

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27. (Amended) A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising:

- D2 cont.
- a) a beneficial agent which has been dried to a low moisture content prior to incorporation in [said] the stable non-aqueous viscous protein formulation; and
 - b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

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28. (Amended) A non-aqueous viscous protein formulation which is stable after sterilization and is capable of being uniformly dispensed over an extended period of time at a low flow rate, the non-aqueous viscous protein formulation comprising:

- a) at least one beneficial agent; and
- b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

11-14
29. (Amended) A method for preparing a stable non-aqueous single phase biocompatible viscous vehicle, the method comprising the steps of (1) selecting two components from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same; (2) blending the two components at elevated temperature under dry conditions to allow them to liquefy; and (3) allowing the liquid from step (2) to cool to room temperature such that a stable non-aqueous single phase biocompatible viscous vehicle formed exhibits a viscosity between about 1,000 and about 10,000,000 poise.

D2 cont
30. (Amended) A method for preparing a stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the method comprising:

combining, under dry conditions, a beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise;

blending them under vacuum at elevated temperature to uniformly suspend the beneficial agent in the vehicle;

and allowing the formulation to cool to room temperature.

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31. (Amended) A method for preparing a stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the method comprising:

combining, under dry conditions, at least about 0.1% (w/w) of a beneficial agent in a non-aqueous single phase biocompatible viscous vehicle, wherein the vehicle comprises two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise;

D2
cont
blending the beneficial agent and non-aqueous single phase biocompatible viscous vehicle under vacuum at elevated temperature to uniformly suspend the beneficial agent in the vehicle; and

allowing the formulation to cool to room temperature.

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32. (Amended) A method for preparing a stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the method comprising:

suspending at least about 10% (w/w) beneficial agent in a non-aqueous single phase biocompatible viscous vehicle, wherein the vehicle comprises two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise under dry conditions;

blending the beneficial agent and non-aqueous single phase biocompatible viscous vehicle under vacuum at elevated temperature to uniformly suspend the beneficial agent in the vehicle; and

allowing the formulation to cool to room temperature.

18
34. (Amended) A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent, the method comprising:

parenterally administering a therapeutically effective amount of a stable non-aqueous viscous protein formulation capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

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35. (Amended) A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent, the method comprising:

providing a stable non-aqueous viscous protein formulation capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise; and

administering the stable non-aqueous viscous protein formulation to a subject, wherein said administering is long-term and continuous.

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~~36.~~ (Amended) A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent, the method comprising:

providing a stable non-aqueous viscous protein formulation capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise; and

administering the stable non-aqueous viscous protein formulation to a subject, wherein said administering by use of an implantable drug delivery system.

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cont. ²¹
~~37.~~ (Amended) A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent, the method comprising:

providing a stable non-aqueous viscous protein formulation capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise; and

administering the stable non-aqueous viscous protein formulation to a subject, wherein said administering includes daily administration of the stable non-aqueous viscous protein formulation and continues for a period selected from the group consisting of about 3 months, about 6 months, and about 12 months.

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38. (Amended) A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent, the method comprising:

providing a stable non-aqueous viscous protein formulation capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise; and

administering the stable non-aqueous viscous protein formulation to a subject, wherein said administering is accomplished using an implantable drug delivery system and includes administering the stable non-aqueous viscous protein formulation daily for a period selected from the group consisting of about 3 months, about 6 months, and about 12 months.